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Attorney Docket Number 00543-22



Examiner Initials*	Cite No.†	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code† (if known)			
	1	6,027,692		GALEN, et al.	01-22-2000	Entire Document
	2	5,997,476		BROWN	07-12-1999	Entire Document
	3	5,971,922		ARITA, et al.	10-26-1999	Entire Document
	4	5,822,935		HIRAI, et al.	03-16-1999	Entire Document
	5	5,251,126		KAHN, et al.	03-10-1993	Entire Document
	6	5,206,144		ZEUTHEN, et al.	04-27-1993	Entire Document
	7	6,081,786		BARRY, et al.	06-27-2000	Entire Document
	8	6,188,988		BARRY, et al.	02-13-2001	Entire Document
	9	5,431,793		WANG, et al.	07-11-1995	Entire Document
	10	5,453,379		YAMAZAKI, et al.	09-26-1995	Entire Document
	11	6,054,039		SHIEH	04-25-2000	Entire Document
	12	6,175,752		SAY, et al.	01-15-2001	Entire Document
	13	5,741,211		RENIRIE, et al.	04-21-1998	Entire Document
	14	5,108,564		SZUMINSKI, et al.	04-28-1992	Entire Document
	15	5128015		SZUMINSKI, et al.	07-07-1992	Entire Document
	16	6,144,869		BERNER, et al.	11-07-2000	Entire Document
	17	5,801,057		SMART, et al.	09-01-1998	Entire Document
	18	4,731,726		ALLEN, III	03-15-1998	Entire Document
	19	6,272,480		TRESP, et al.	08-07-2001	Entire Document
	20	6,233,471		BERNER, et al.	05-15-2001	Entire Document

[illegible]

Date Considered	02/15/2008
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 9

Complete if Known

Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
Attorney Docket Number	00543-22

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
A	COX, et al.:	"Frequency of Severe Hypoglycemia in Insulin-Dependent Diabetes Mellitus Can be Predicted from Self-Monitoring Blood Glucose..." J of Clinical End. and Met., Vol. 79, No. 6, pp 1659-1662. (1994)	
B	KOVATCHEV, et al.:	"Assessment of Risk for Severe Hypoglycemia Among Adults with IDDM", Diabetes Care, Vol. 21, No. 11, November (1998)	
C	KOVATCHEV, et al.:	"Symmetrization of the Blood Glucose Measurement Scale and its Applications", Diabetes Care, Vol 20, No. 11, November (1997)	
D	KOVATCHEV, et al.:	"Risk Analysis of Blood Glucose Data: A Quantitative Approach to Optimizing the Control of Insulin Dependent Diabetes", J. of Theoretical Medicine, pp 1 - 10, January (2000)	
E	KOVATCHEV, et al.:	"Episodes of Severe Hypoglycemia in IDDM are Preceded, and Followed, within 48 hours by Measurable Disturbances..."	
F	KOVATCHEV, et al.:	"Assoc. of Self-Monitoring Blood Glucose Profiles with Glycosylated Hemoglobin in Patients...", Methods in Enzymology, Vol 321, pp 410-417, (2000)	
G	LEHMANN, E.D., et al.:	"Computer assisted diabetes care: a 6-year retrospective", Computer Methods and Programs in Biomedicine, 50, 209-230 (1996)	
H	DEUTSCH, T., et al.:	"Time series analysis and control of blood glucose levels in diabetic patients", Computer Methods and Programs in Biomedicine, 41, 167-182 (1994)	
I	LEHMANN, E.D., et al.:	"AIDA: an interactive diabetes advisor", Computer Methods and Programs in Biomedicine, 41, 183-203, (1994)	
J	LEHMANN, E.D., et al.:	"Retrospective validation of physiological model of glucose-insulin interaction in type 1 diabetes mellitus", Med. Eng. Phys., Vol. 16, 193-202, May (1994)	
K	LEHMANN, E.D., et al.:	"Extended Conference Report: Computers in Diabetes '96", Med. Inform, Vol. 22, No. 1, 105-118, (1997)	

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L	LEHMANN, E.D., et al.:	"Application of computers in diabetes care -- a review. I. Computers for data collection and interpretation", Vol. 20, No. 4, 281-302, (1995)	
M	DEUTSCH, T. et al.:	"UTOPIA: a consultation system for visit-by-visit diabetes management", Med Inform, Vol. 21, No. 4, 345-358 (1996)	
N	LEHMANN, E.D., et al.:	"Compartmental models for glycaemic prediction and decision-support in clinical diabetes care: promise and reality" Computer Methods and Programs in Biomedicine, Vol. 56, 193-204, (1998)	
O	LEHMANN, E.D., et al.:	"A physiological model of glucose--insulin interaction in type I diabetes mellitus", J. of Biomedical Engineering Vol. 14, No. 3, 235-242 (1992)	
P	TRAJANOSKI, ZLATKO, et al.:	"Simulation studies on neural predictive control of glucose using the subcutaneous route", Comp Methods and Programs in Biomed., Vol. 56, Iss 2, 133-139, May (1998)	
Q	TRAJANOSKI, ZLATKO, et al.:	"Fuzzy filter for state estimation of a glucoregulatory system", Comp. Methods and Programs in Biomedicine, Vol. 50, 265-273, (1996)	
R	TRAJANOSKI, ZLATKO, et al.:	"Regularization networks for Glucose System Identification", Institute of Biomedical Engineering, 1083-, 0-7803-2050-6/94 ABSTRACT ONLY	
S	REGITTNIG, W. et al.:	"Glucose-mediated glucose disappearance during the intravenous...", 18th Annual International Conference of the IEEE Eng. in Medicine and Biology Society, Amsterdam, 0-7803-3811-1/97 1996 (annotated by examiner LAC)	
T	FISCHER, UWE, et al.:	"Experimental validation of a glucose- insulin control model to simulate patterns in glucose turnover", Comp. Methods and Programs in Biomedicine, Vol. 32, 249-258 (1990)	
U	SALZSIEDER, E., et al.:	"A Model-based System for the Individual Prediction of Metabolic Responses to Improve Therapy in Type I Diabetes", Central Inst. of Diabetes, Horm. Metab. Res, 24 (Suppl) 10-19 (1990)	
V	SALZSIEDER, ECKHARD, et al.:	"Computer-aided systems in the management of type I diabetes: the application of a model-based strategy", Computer Methods and Programs in Biomedicine, Vol. 32, 215-224, (1990)	

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W		SALZSIEDER, ECKHARD, et al.: "Model-Based Prevention in IDDM of Exercise-Induced Hypoglycemia". ABSTRACT ONLY	
X		BLECKERT, GABRIELE, et al.: "Mixed graphical models for simultaneous model identification and control applied to the glucose-insulin metabolism", Computer Method and Programs in Biomed Vol. 56, 141-155 (1998)	
Y		MARTIN, IVA K, et al.: "Application of the SAAM modeling program to minimal model analysis of intravenous glucose tolerance test data", Computer Methods and Programs in Biomedicine, Vol. 33 193-203(1990)	
Z		WARD, G. M., et al.: "Physiologic Modeling of the Intravenous Glucose Tolerance Test in Type 2 Diabetes: A new Approach to the Insulin Compartment", Metabolism, Vol 50, No. 5, 512-519, May (2001)	
AA		WARD, G. M., et al.: "A Modified Minimal Model Analysis of Insulin Sensitivity and Glucose-Mediated Glucose Disposal in Insulin-Dependent Diabetes", Metabolism, Vol. 40, No. 1, 4-9, January (1991)	
BB		THOMASETH, KARL, et al.: "Parameter Information Content During Model Identification Experiments", 3rd IFAC Symposium on Modelling and Control in Biomedical Systems, Warwick UK, 107-112 (1997)	
CC		PACINI, GIOVANNI, et al.: "Estimation of B-cell Secretion and insulin hepatic extraction by the minimal modelling technique", Computer Methods and Programs in Biomedicine, Vol. 32, 241-248 (1990)	
DD		BELLAZZI, R., et al.: "Bayesian Analysis of Blood Glucose Time Series from Diabetes Home Monitoring", IEEE Transactions on Biomedical Engineering, Vol. 47, No. 7, 971-, July (2000)	
EE		BELLAZZI, R, et al.: "The Subcutaneous Route to Insulin-Dependent Diabetes Therapy", IEEE Engineering in Med. and Bio., Vol. 20, No. 1, 54-64, Jan (2001)	
FF		RIVA, A., et al.: "High Level Control Strategies for Diabetes Therapy", Proceedings of the Fifth Conference on Artificial Intelligence in Medicine Europe, No. 934 in Lecture Notes in Artificial Intelligence, p 185-196, (1995)	
GG		ARLETH, T. et al.: "A model of the endogenous glucose balance incorporating the characteristics of glucose transporters", Computer Methods and Programs in Biomedicine, Vol. 62, 219-234, (2000)	

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	HH	STURIS, JEPPE, et al.: "Computer model for mechanisms underlying ultradian oscillations of insulin and glucose", Am. J. of Physiol., Modeling Methodology Forum, E801-E809, (1991)	
	II	QUON, MICHAEL, et al.: "Non-Insulin-Mediated Glucose Disappearance in Subjects with IDDM Discordance Between...", Diabetes, Vol. 43, 890-, July (1994)	
	JJ	MUZIC, R. et al.: "COMKAT: Compartment Model Kinetic Analysis Tool", The Journal of Nuclear Medicine, Vol. 42, No. 4, April (2001)	
	KK	FREELAND, ANGELA, et al.: "Inference of Blood Glucose Concentrations from Subcutaneous Glucose...", Annals of Biomedical Engineering, Vol. 27, 525-537, (1999)	
	LL	BERGER, MARCUS, et al.: "Computer Simulation of Plasma Insulin and Glucose Dynamics After Subcutaneous Insulin Injection", Diabetes Care, Vol. 12, No. 10, November (1989)	
	MM	FINEGOOD, D., et al.: "Reduced glucose effectiveness associated with reduced insulin release: an artifact of the minimal-model method", Am. J. of Physiol. Endocrin. Metab. 271, E485-E495, (1996)	
	NN	NAYLOR, J. S., et al.: "Comparison of parametrized models for computer-based estimation of diabetic patient glucose response", Med. Inform., Vol. 22, No. 1, 21-34, (1997)	
	OO	ANDREASSEN, S.: "Model-Based Biosignal Interpretation", Meth Inform Med, Vol. 33, 103-110, (1994)	
	PP	WORTHINGTON, D.: "The use of models in the self-management of insulin-dependent diabetes mellitus", Computer Methods and Programs in Biomedicine, Vol. 32, 233-239, (1990)	
	QQ	CARSON, E.R.: "Information technology and computer-based decision support in diabetic management", Computer Methods and Programs in Biomedicine, Vol. 32, 179-188, (1990)	
	RR	GOMEZ, E.J, et al.: "Telemedicine for diabetes care: the DIABTel approach towards diabetes telecare", Med. Inform., Vol. 21, No. 4, 283-295, (1996)	

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Sheet 5 of 9

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Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
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	SS	TRAJANOSKI, ZLATKO, et al.: "Neural Predictive Controller for Insulin Delivery Using the Subcutaneous Route", IEEE Transactions on Biomedical Engineering, Vol. 45, No. 9, September (1998)	
	TT	BERGER, M.P.: "Combining Statistical, Rule-Based, and Physiologic Model-Based Methods to Assist in the Management...", Computer and Biomedical Research, Vol. 23, 346-357, (1990)	
	UU	FISHER, MICHAEL: "A Semiclosed-Loop Algorithm for the Control of Blood Glucose Levels in Diabetics", IEEE Transactions on Biomedical Engineering, Vol. 38, No. 1, January 1991	
	VV	HERNANDO, M.E. et al.: "DIABNET, a qualitative model-based advisory system for therapy planning in gestational diabetes", Med. Inform. Vol. 21, No. 4, 359-374, (1996)	
	WW	KIENITZ, Karl H., et al.: "A Robust Controller for Insulin Pumps Based on H-Infinity Theory", IEEE Transactions on Biomedical Engineering, Vol. 40, No. 11, November (1993)	
	XX	PARKER, ROBERT, et al.: "Control-relevant modeling in drug delivery", Advanced Drug Delivery Reviews, Vol. 48, 211-228, (2001)	
	YY	CARSON, E.R., et al.: "Computers in Diabetes - an Introduction", Computer Meth Prg. Biomed., Vol. 62, 153-155, (2000)	
	ZZ	HAUSER, THOMAS, et al.: "Assessment of Experts' Approach to Insulin Therapy...", Diabetes Care, Vol. 15, No. 2, pp 221-, February (1992)	
	aaa	GARCIA, ALEJANDRO: "The Bergman's Insulin-Glucose Regulation Model: DNN-state Observer", Proceedings of the 22nd Annual EMBS International Conf., July 23-28, Chicago, IL, (2000)	
	bbb	SANDHAM, W.A., et al.: "Neural Network and Neuro-Fuzzy Systems for Improving Diabetes Therapy", Proceedings of the 20th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vol. 20, No. 3, part 3/6, p 1438-1441(1998)	
	ccc	PARKER, R.S. et al.: "Time and Frequency Domain Analysis of Blood Glucose Regulation Algorithms", Proceedings- 19th International Conference- IEEE/EMBS, Chicago, IL, Oct. 30- Nov. 2, (1997)	

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ddd		PARKER, ROBERT S., et al.: "The Intravenous Route to Blood Glucose Control", IEEE Engineering in Medicine and Biology, pp 65-, January (2001)	
eee		PARKER, ROBERT S., et al.: "A Model-Based Algorithm for Blood Glucose Control in Type 1 Diabetic Patients", IEEE Transactions on Biomedical Engineering, Vol. 46, No. 2, pp 148-, February (1998)	
fff		PUCKETT, WANDA, et al.: "A model for multiple subcutaneous insulin injections developed from individual diabetic patient data", Am. J. Physiol Endocrinol Metab, 269 Modeling in Physiology, E1115-E1124, (1995)	
ggg		KAN, SHUGEN, et al.: "Novel Control System for Blood Glucose Using a Model Predictive Method", ASAIO Journal, pp 657 -, (2000)	
hhh		CANDAS, B. et al.: "An Adaptive Plasma Glucose Controller Based on a Nonlinear Insulin/Glucose Model", IEEE Transactions on Biomedical Engineering, Vol. 41, No. 2, pp 116 -, February (1994)	
iii		ROBINSON, DAVID, et al.: "Knowledge of Diabetes mellitus and glycaemic control", Med. Principles Pract. Vol. 6, 186-197 (1997)	
jjj		TOTH, MICHAEL, et al.: "Determinants of insulin-stimulated glucose disposal in middle-aged, premenopausal women", Am J Physiol Endocrinol Metab., Vol. 281, E113-E121, (2001)	
kkk		BANDO, YUKIHIRO, et al.: "The Relationship of Fasting Plasma Glucose Values and Other Variables to 2-h...", Diabetes Care, Vol. 24, No. 7, pp 1156 -, July (2001)	
lll		LISZKA-HACKZELL, JAN JOHN: "Prediction of Blood Glucose Levels in Diabetic Patients Using a Hybrid AI Technique", Computers and Biomedical Research, Vol. 32, 132-144 (1999)	
mm		WALDHAUSL, WERNER, et al.: "Blood Glucose Response to Stress Hormone Exposure in Healthy Man...", IEEE Transactions on Biomedical Engineering, Vol. 39, No. 8, August (1992)	
nnn		HASTINGS, GREGORY, et al.: "A Self-Organising Fuzzy Estimator for Hypoglycaemia Monitoring in Diabetic Patients", Proceedings of the 20th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vol. 20, No 3, pp. 1371 -, (1998)	

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	uuu	BASU, TK., "Computer Simulation of Blood Glucose Level in Stress Conditions", pp 491 ABSTRACT ONLY	
	ppp	TRESP, Volker, et al.: "Neural-Network Models for the Blood Glucose Metabolism of a Diabetic", IEEE Transactions on Neural Networks, Vol. 10, No. 5, pp 1204-1213, September (1999)	
	qqq	YATES, Tony, et al.: "Prediction of a glucose appearance function from foods using deconvolution", IMA Journal of Mathematics Applied in Medicine and Biology, Vol. 17, 169-184, (2000)	
	rrr	HEJESEN, OLE, et al.: "DiasNet: an internet tool for communication and education in diabetes, Medical infobahn for Europe, Proceedings of MIE2000 and GMDX2000, pp 563-567, Studies in health technology and informatics, 77 (2000) (annotated by examiner LAC)	
	sss	CAVAN, D.A., et al.: "Use of the DIAS model to predict unrecognized hypoglycaemia in patients with insulin-dependent diabetes", Computer Methods and Programs in Biomedicine, Vol. 50, 241-246, (1996)	
	ttt	HEJESEN, Ole, et al.: "Analysing the hypoglycaemic counter-regulation: a clinically relevant phenomenon?", Computer Methods and Programs in Biomedicine, Vol. 50, 231-240, (1996)	
	uuu	HEJESEN, Ole, et al.: "Dynamic Propagation in Causal Probabilistic networks with Instantiated Variable", Artificial Intelligence in Medicine: Proceedings of the 5th Conference on Artificial Intelligence in Medicine, 151-162, (1995)	
Ref. vvv considered LAC	yvv	CAVAN, DA, et al.: "Preliminary experience of the DIAS computer model in providing insulin dose advice to patients with insulin dependent diabetes", Computer Methods and programs in Biomedicine, Vol. 56, p 157-164, (1998)	
	w3	ANDREASSEN, STEEN, et al.: "A probabilistic approach to glucose prediction and insulin dose adjustment; description of metabolic model and pilot evaluation study", Computer Methods and Programs in Biomedicine, Vol. 41, 153-165, (1994)	
	xxx	TUDOR, ROMULUS, et al.: "DIAS-NIDDM- a model-based decision support system for insulin dose adjustment in insulin-treated subjects with NIDDM", Computer Methods and Programs in Biomedicine, Vol. 56, 175-192, (1998)	
	yyy	GOLD, A.E., et al.: "A Structural Equation Model for Predictors of Severe Hypoglycaemia in Patients with Insulin-dependent Diabetes Mellitus", Diabetic medicine, Vol. 14, 309-315, (1997)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 8 of 9

Complete if Known

Application Number 10/524,094
 Filing Date 2/9/2005
 First Named Inventor Boris P. Kovatchev, et al.
 Group Art Unit 1652
 Examiner Name Unknown
 Attorney Docket Number 00543-22

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	zzz	BREMER, TROY, et al.: "Is Blood Glucose Predictable from Previous Values? A solicitation for data", Diabetes, Vol. 48, pp 445-451, March (1999)	
	I	BOYLE, PATRICK, et al.: "Plasma Glucose Concentrations at the onset of Hypoglycemic symptoms in Patients with Poorly Controlled Diabetes and in Nondiabetics", Plasma Glucose Concentrations and Hypoglycemia, Vol. 318, No. 33, 1487-1492, (1988)	
	II	CARSON, EWART: "A systems model of Blood Glucose control", Int. J. Bio-Medical computing, Vol. 7, pp 21-34, (1976)	
	III	WORTHINGTON, D.R.L.: "Minimal Model of Food Absorption in the gut", Med. Inform., Vol. 22, No. 1, 35-45 (1997)	
	IV	WORTHINGTON, D.R.L.: "Controlling blood Glucose: insights from an engineering control systems perspective", Med. Inform. Vol. 22, No. 1, 5-19 (1997)	
	V	DCCT RESEARCH GROUP: "The effect of intensive treatment of diabetes on the development and progression of Long-term complications of insulin-dependent diabetes Mellitus", New England Journal of Medicine, Vol. 329, 977-986 (1993)	
	VI	REICHARD, P, et al.: "Mortality and Treatment Side Effects During Long-term Intensified Conventional Insulin Treatment in the Stockholm Diabetes Intervention Study", Diabetes, Vol. 43, 313-317 (1994)	
	VII	UK PROSPECTIVE DIABETES STUDY GROUP: "Effect of Intensive Blood Glucose Control with Metformin on Complications in Patients with Type 2 Diabetes (UKPDS34)", Lancet, Vol. 352, 854-865, (1998)	
	VIII	DCCT RESEARCH GROUP: "Epidemiology of Severe Hypoglycemia In the diabetes control and complications trial", Amer. J. of Med., Vol. 90, 450-459, (1991)	
	IX	DCCT RESEARCH GROUP: "Hypoglycemia in the Diabetes control and complications Trial", Diabetes, Vol. 46, 271-286, (1997)	
	X	CRYER, PE: "Hypoglycemia is the limiting factor in the management of Diabetes", Diabetes Metab Res Rev, Vol. 15, 42-46, (1999)	

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Sheet 9 of 9

Complete if Known

Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
Attorney Docket Number	00543-22

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	XI	SVENDSON, AABY, et al.: "Glycosylated Hemoglobin and Steady-State Mean Blood Glucose Concentration in Type 1 (Insulin-Dependent) Diabetes", Diabetologia, Vol. 23, 403-405, (1982)	
	XII	SANTIAGO, J.V.: "Lessons from the Diabetes Control and Complications Trial", Diabetes, Vol. 42, 1549-1554, (1993)	
	XIII	BOLLI, G.B.: "How to Ameliorate the Problem of Hypoglycemia in Intensive as well as Nonintensive Treatment of Type 1 Diabetes", Diabetes Care, Vol. 22, Supplement 2, B43-B52, (1999)	
	XIV	BREMER, T, et al.: "Is blood glucose predictable from previous values? A solicitation for data", Diabetes, Vol. 48, 445-451, (1999)	
	XV	KOVATCHEV, B.P., et al.: "Estimating the speed of Blood Glucose Transitions and its relationship with Severe Hypoglycemia", Diabetes, 48: Supplement 1, A363, (1999)	

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